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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,872	09/16/2003	Liliana Tejidor	00825Div.JAR	3114

7590 11/19/2007

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

MAIL DATE	DELIVERY MODE
11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,872	TEJIDOR ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *101-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *101-104* is/are allowed.

6)☒ Claim(s) *106-108* is/are rejected.

7)☒ Claim(s) *109-110* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 9/6/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 1-100 had been cancelled.
2. Claims 101-109 are under examination.

1. Applicant filed Terminal Disclosure with respect to the US Patent 6645768 has been received and approved.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 106 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al. (US 20020042144) in view of Zuk et al. (US 4208479).

Mann et al. teach a method of measuring the blood clotting/coagulation of sample. Mann et al. establish a concentration-clotting time curve by using coagulation activator, i.e. tissue factor, where the tissue factor having a lower concentration less than 10 picomolar (pM) (See Figure 3; Section 0162).

Applicant is reminded that a recitation of the intended use of the claimed invention, i.e., resulting in a thrombin formation but not result in a complete fibrin polymerization of the blood sample, and such concentration can be used to assess both the anticoagulant and procoagulant potential of a blood sample, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). The reference of Mann et al. has shown the same effective amount of coagulation activator has been used, therefore Mann et al. reference anticipates the instant invention.

However, Mann et al. do not explicitly teach formulate the coagulation activator reagents into a kit for assay.

Zuk et al. teach that in performing assays, it is convenient and to combine the necessary reagents together in a kit (col. 22, lines 20-35). Zuk et al. further teach that this may improve assay accuracy.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Mann et al. to place the coagulation activator reagents into a kit as taught by Zuk et al. for convenience, standardization, and improved assay accuracy.

With respect to claim 108, Mann et al. teach using fixed phospholipids (Section 0227; Figure 10 and Example 14).

5. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al. in view of Zuk et al., and further in view of Matschiner (US 5716795).

Both Mann et al. and Zuk et al. references have been discussed but no explicit teachings of using thrombomoldulin is mentioned.

Matschiner et al. teach that blood clotting mechanisms are controlled by various pathways, including vitamine K-dependent coagulation, and protein C and protein S. Matschiner et al. teach thrombomodulin is often used as an activator for study protein C and S pathway in blood clotting/coagulation (Col. 3 to Col. 6). Such protein C/S pathway is commonly used to study for prolongation of factor Xa or partial thromboplastin time (APTT)(Col. 7, line 5-15).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Mann et al. and Zuk et al. with the thrombomodulin for study blood clotting in both protein C and protein S pathways because Mann and Matschiner et al. are in an analogous blood coagulation study field, and it has been recognized in the field that protein C and protein S pathway plays an important role in blood clotting, and one ordinary skill in the art would have been motivated to incorporate more pertinent reagent, such as thromobomodulin, to study alternative related blood clotting pathway.

Response to Applicant's Arguments

6. The objections of claims 105-106 are withdrawn because applicant had amended the claims and the language is clear.

7. The allowable claims 106 and 108 are rejected based on the new rejections set forth in this Office Action.

Allowable Subject Matter

Claims 101-104, and 109-110 are allowable. The following is an examiner's statement of reasons for allowance: no prior art teaches nor suggests a reagent for an assay to determine a hemostatic potential of a blood or plasma sample comprising a coagulation activator wherein the coagulation activator is present at a concentration level to trigger thrombin formation fibrin polymerization but not sufficient to result in a complete fibrin polymerization of said blood or plasma sample and a second thrombomodulin wherein said reagent may be utilized to assess a hypocoaguable, normal, and hypercoaguable condition in a single assay. The closest prior art is Mann et al. where the reference only teaches using coagulation activator, but no thrombomodulin, for assessing coagulant activity, i.e. hypocoagulation in the patient. Furthermore, no prior art teaches or suggests using a protein C activator, such as thromobomodulin, in a range of 5 to 20 nM, in combination with coagulation activator to study blood clotting. The closest prior art is the reference of Matschiner et al.. However, the concentration used by Matschiner et al. is approximately 3-4 fold higher than 20 nM.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

November 6, 2007

LONG V. LE 11/09/07
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